Remarks

Introduction

Claims 114-171 were previously pending in this application. With this amendment, claim 114 has been amended, claims 118 and 122-171 have been cancelled without prejudice, and claims 172-185 have been added. No new subject matter has been introduced with these amendments.

Independent claim 114 has been amended to include the subject matter of claim 118 and claim 126, as well as to include subject matter at least described at page 2, lines 16-21; page 3, lines 11-14; page 6, lines 18-23; page 7, lines 1-4; page 7, lines 5-10; page 12, line 30-32; and page 14, lines 13-19, and 28-30.

Independent claim 172 has been added and includes the subject matter of present claim 114 and previous claim 126. Independent claim 179 has been added and includes the subject matter of present claim 114 and previous 126.

In view of the above, claims 114-117, 119-121, and 172-185 are currently pending, and each of the present claims is within the scope of the originally filed claims.

Applicant respectfully requests entry of this Amendment and reconsideration of the rejections.

Election/Restriction

Claims 127-171 have been withdrawn from consideration as being directed to inventions that are independent or distinct from the originally claimed invention.

By way of this amendment, claims 127-171 have been cancelled without prejudice. Applicant reserves the right to pursue the subject matter of any of claims 127-171 in one or more divisional applications as appropriate.

Rejections Under 35 U.S.C. § 103

Claims 114-126 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Hu (US 20010044482), Gordon (US 4,123,408), or Shah (US 4,462,665), each taken in view of Dziabo (US 5,338,480), Krezanoski (US 3,954,644), Huth (US 4,460,573), and Park (US 5,882,687). Claims 114-116 and 122-126 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Tanaka (US 6,008,170), or Salpekar (US 6,440,366), each taken in view of

Dziabo (US 5,338,480), Krezanoski (US 3,954,644), Huth (US 4,460,573), and Park (US 5,882,687).

Applicant does not concede to the correctness of the rejections. However, to advance the prosecution of the present application, the claims have been amended as set forth above. Applicant traverses each the rejections as each relates to the present claims, and submits that the rejections cannot be properly maintained.

Addressing the second rejection of the claims under 35 U.S.C. § 103(a), that is the rejections of claims 114-116 and 122-126 over Tanaka (US 6,008,170), or Salpekar (US 6,440,366), each taken in view of Dziabo (US 5,338,480), Krezanoski (US 3,954,644), Huth (US 4,460,573), and Park (US 5,882,687), independent claim 114 has been amended to include the subject matter of claim 118. The Office Action indicates that claim 118 was patentable over Tanaka (US 6,008,170), or Salpekar (US 6,440,366), each taken in view of Dziabo (US 5,338,480), Krezanoski (US 3,954,644), Huth (US 4,460,573), and Park (US 5,882,687).

Therefore, Applicant submits that currently amended independent claim 114, and new independent claims 172 and 179, are similarly patentable over Tanaka (US 6,008,170), or Salpekar (US 6,440,366), each taken in view of Dziabo (US 5,338,480), Krezanoski (US 3,954,644), Huth (US 4,460,573), and Park (US 5,882,687), and that the second rejection under 35 U.S.C. § 103(a) has been overcome. Applicant respectfully requests that this rejection be withdrawn.

The present claims are directed to contact lens package systems, such as contact lens blister packages, as shown in FIG. 1. As described in the specification, these package systems are provided by contact lens manufacturers to store contact lenses so that the contact lenses can be distributed for use by contact lens wearers. The package system recited in the present claims include a single use disposable hydrogel contact lens, a sterile packaging liquid medium, and a container holding the contact lens and the sterile packaging liquid medium.

In a typical manufacturing process, a contact lens and a packaging liquid medium are placed in the container, such as a cavity of a blister pack, and the container is closed, such as by attaching a removable sealing member to the container. The sealed container containing the contact lens and the packaging liquid is then sterilized, such as by autoclaving the container, which includes heating the container and its contents to about 120 degrees under pressure to produce a package system that has a sterile contact lens in a sterile packaging liquid. The

autoclaved or sterilized package system can then be stored and subsequently distributed to a contact lens wearer or physician who will distribute the package to a lens wearer. The seal is removed and the contact lens is removed from the packaging liquid and is placed on an eye of a contact lens wearer.

For lenses other than single use disposable lenses or daily disposable contact lenses, a contact lens is removed from the eye after a period of time, such as after about 8 hours or more, and is treated with a cleaning solution. Typically, the contact lens is rinsed in the cleaning solution, and then stored in the cleaning solution for a period of time in a contact lens cleaning case.

As understood by persons of ordinary skill in the art, contact lens packaging solutions and contact lens cleaning solutions are different and distinct, one from the other. For example, contact lens cleaning solutions include disinfecting agents. Disinfecting agents aren't included in a contact lens packaging solution because the package, and the solution contained by the package container, is sterilized prior to distribution. Therefore, disinfecting agents are not necessary, and are actually avoided because of additional requirements imposed on the contact lens manufacturer and because the disinfecting agents can cause irritation to the eye of the contact lens wearer.

In addition, single use disposable contact lenses or daily disposable contact lenses are packaged in a package system that includes a packaging solution. The contact lens is removed from the packaging solution and is placed on an eye of a contact lens wearer. After an amount of time, such as after about 8 to 14 hours, the contact lens is removed from the eye and is disposed. Single use disposable contact lenses are not prescribed for use multiple times and therefore are not used with cleaning solutions.

In more detail, the package system recited in claim 114, comprises a single use disposable hydrogel contact lens that is ready for use in an eye (e.g., it has been sterilized in it's package) and the contact lens comprises a cast molded contact lens body that comprises a hydrophilic polymeric material and a water soluble polymer component. The package system also comprises a sterile packaging liquid medium or packaging solution. The sterile packaging liquid medium comprises an amount of the water soluble polymer component in addition to that present in the contact lens body. The package system also comprises a container holding the contact lens and the sterile packaging liquid medium. In the package system of claim 114, the

water soluble polymer component of the cast molded contact lens body and the sterile packaging liquid medium comprises polyvinyl pyrrolidone. Therefore, it can be understood that the package system of claim 114 comprises both a contact lens that comprises polyvinyl pyrrolidone and a sterile packaging liquid medium that comprises polyvinyl pyrrolidone.

Claim 172 is similar to claim 114, but claim 172 recites that the water soluble polymer component comprises a polyalkylene glycol. Therefore, it can be understood that the package system of claim 172 comprises both a contact lens that comprises polyalkylene glycol and a sterile packaging liquid medium that comprises polyalkylene glycol.

Claim 179 is similar to claim 114, but claim 179 recites that the water soluble polymer component comprises a polyvinyl alcohol. Therefore, it can be understood that the package system of claim 179 comprises both a contact lens that comprises polyvinyl alcohol and a sterile packaging liquid medium that comprises polyvinyl alcohol.

As discussed herein, Applicant submits that the rejections under 35 U.S.C. § 103 over any combination of the cited references cannot be properly maintained with respect to the present claims. In view of the amendments and remarks herein, applicant submits that the present claims are unobvious from and patentable over the cited references taken alone or in any combination, and respectfully requests that the rejections under 35 U.S.C. § 103 be withdrawn.

As set forth in MPEP § 2143, to establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Applicant submits that the present claims are unobvious from and patentable over the cited references, at least because the cited references taken alone or in any combination do not teach or suggest all of the features recited in the present claims. Thus, at least one of the three basic criteria for establishing obviousness have not been met.

For example, the cited references taken alone or in any combination do not teach or suggest a package system as recited in any of independent claims 114, 172, or 179. The cited

references taken alone or in any combination do not teach or suggest contact lens package systems that include the recited contact lens, the recited sterile packaging liquid medium, wherein **both** the contact lens **and** the sterile packaging liquid medium comprise a polyvinyl pyrrolidone (claim 114), a polyalkylene glycol (claim 172), or a polyvinyl alcohol (claim 179).

For example, Gordon specifically teaches how to make lathed contact lenses (see col. 9, lines 19-25), and Shaw specifically teaches how to make laminated contact lenses (see col. 7, line 55 to col. 8, line 62). Lathed contact lenses and laminated contact lenses are physically different and distinct from cast molded contact lenses. In addition, Krezanoski, Huth, and Dziabo each specifically teach contact lens cleaning solutions, not contact lens packaging solutions. The cleaning solutions disclosed in each of these references include disinfecting agents which are not present in contact lens packaging solutions. Furthermore, the cleaning solutions in each of the cited references include a cleaning agent, which is not present in contact lens packaging solutions, as recited in the present claims, since the single use disposable hydrogel contact lens has not been worn yet and therefore does not need to be cleaned.

In addition, none of the cited references, taken alone or in any combination, teach or suggest the combination of both a single use disposable hydrogel contact lens and a sterile packaging liquid medium that both include polyvinyl pyrrolidone (as recited in claim 114), that both include a polyalkylene glycol (as recited in claim 172), or that both include a polyvinyl alcohol (as recited in claim 179). For example, and in contrast, Park specifically teaches compositions that include carboxymethylcellulose (see col. 5, line 66 to column 6, line 58), and Salpekar specifically teaches compositions that include poly(oxyalkylene) copolymers, such as poloxamines and poloxamers (see Abstract and col. 1, lines 41-42). The polyvinyl pyrrolidone recited in claim 114, the polyalkylene glycol recited in claim 172, and the polyvinyl alcohol recited in claim 179 are each different and distinct from the polyanionic material described in Park and from the poly(oxyalkylene) copolymers described in Salpekar.

Thus, differences between the presently claimed package systems and the package systems of the cited references, taken alone or in any combination, include the type of contact lens provided in the claimed package systems, differences in the type of liquid medium provided in the claimed package systems, and differences in the contact lens material and packaging liquid material in the claimed package systems.

Based on the foregoing, applicant submits that the rejections under 35 U.S.C. § 103 cannot be properly maintained since the cited references taken alone or in any combination do not teach or suggest all of the elements recited in the present claims.

Furthermore, applicant submits that a person of ordinary skill in the art would not be motivated to combine the teachings of the cited references, let alone do so and obtain the presently claimed package systems. Among other things, a person of ordinary skill in the art would not be motivated to use a contact lens cleaning solution as a contact lens packaging liquid since cleaning solutions include disinfecting agents and cleaning agents, which are not included in packaging liquids. In addition, a person of ordinary skill in the art would not be motivated to place a single use disposable hydrogel contact lens in contact with a cleaning solution since that would be directly contrary to the prescribed use of the contact lens, that is to wear the contact lens once and then dispose of the contact lens without cleaning the contact lens. Therefore, when each of the references is considered as a whole, the references taken alone or in combination, do not suggest the desirability of making the subject matter of the present claims.

In view of the above, applicant submits that the rejections under 35 U.S.C. § 103, as applied to the present claims, are unsupported by the cited references and should be withdrawn.

Conclusion

In view of the foregoing amendments and remarks, Applicant submits that the present claims, that is claims 114-117, 119-121, and 172-185, are in condition for allowance. Notice of which is respectfully requested. If a telephone interview would be of assistance in advancing prosecution of the subject application, Applicant's undersigned representative invites the Examiner to telephone him at the number provided below.

Although no additional fee should be necessary, the Commissioner is hereby authorized to charge any additional fees deemed necessary, or credit any overpayment, to Deposit Account No. 50-4064. Please show the docket number of this application with any charge or credit to the Deposit Account.

Respectfully submitted,

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/Greg S. Hollrigel, Reg. # 45374/

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